

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

IDENIX PHARMACEUTICALS LLC and  
UNIVERSITA DEGLI STUDI DI  
CAGLIARI,

Plaintiffs,

v.

GILEAD SCIENCES, INC.,

Defendant.

C.A. No. 14-846-LPS

**JOINT PROPOSED FINAL JURY INSTRUCTIONS**

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**1. GENERAL INSTRUCTIONS**

**1.1 INTRODUCTION – AGREED**

Members of the jury, now it is time for me to instruct you about the law that you must follow in deciding this case. Each of you has been provided a copy of these instructions. You may read along as I deliver them if you prefer.

I will start by explaining your duties and the general rules that apply in every civil case. Then I will explain some rules that you must use in evaluating particular testimony and evidence.

Then I will explain the positions of the parties and the law you will apply in this case. And last, I will explain the rules that you must follow during your deliberations in the jury room, and the possible verdicts that you may return.

Please listen very carefully to everything I say.

You will have your written copy of these instructions with you in the jury room for your reference during your deliberations. You will also have a verdict form, which will list the questions that you must answer to decide this case.

## **1.2 JURORS' DUTIES – AGREED IN PART**

You have two main duties as jurors. The first is to decide what the facts are from the evidence that you saw and heard here in court. Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way. You are the sole judges of the facts. **[Gilead proposal: Do not guess or speculate, and do not be influenced in any way, by any personal feeling of sympathy for, or prejudice against, either side in this case.]**

Your second duty is to take the law that I give you, apply it to the facts, and decide under the appropriate burden of proof which party should prevail on any given issue. It is my job to instruct you about the law, and you are bound by the oath you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. This includes the instructions that I gave you before and during the trial, and these instructions. All of the instructions are important, and you should consider them together as a whole.

Perform these duties fairly. **[Gilead proposal: Do not let any bias, sympathy, or prejudice you may feel toward one side or the other influence your decision in any way.]**

### **1.3 EVIDENCE DEFINED – AGREED**

You must make your decision based only on the evidence that you saw and heard here in court. Do not let rumors, suspicions or anything else that you may have seen or heard outside of court influence your decision in any way.

The evidence in this case includes only what the witnesses said while they were testifying under oath (including deposition transcript testimony that has been played by video or read to you), the exhibits that I allowed into evidence, the stipulations to which the lawyers agreed and any facts that I have judicially noticed.

Nothing else is evidence. The lawyers' statements and arguments are not evidence. Their questions and objections are not evidence. My legal rulings are not evidence. Any of my comments and questions are not evidence.

During the trial I may have not let you hear the answers to some of the questions that the lawyers asked. I also may have ruled that you could not see some of the exhibits that the lawyers wanted you to see. And, sometimes I may have ordered you to disregard things that you saw or heard, or that I struck from the record. You must completely ignore all of these things. Do not speculate about what a witness might have said or what an exhibit might have shown. These things are not evidence, and you are bound by your oath not to let them influence your decision in any way.

*[To be included if such instructions have been given: During the course of the trial, if I instructed you that I admitted certain testimony and certain exhibits for a limited purpose, you may consider such evidence only for the specific limited purposes for which it was admitted.]*

Make your decision based only on the evidence, as I have defined it here, and nothing else.

#### **1.4 DIRECT AND CIRCUMSTANTIAL EVIDENCE – AGREED**

You may have heard the terms “direct evidence” and “circumstantial evidence.”

Direct evidence is simply evidence like the testimony of an eyewitness which, if you believe it, directly proves a fact. If a witness testified that he saw it raining outside, and you believed him, that would be direct evidence that it was raining.

Circumstantial evidence is simply a chain of circumstances that indirectly proves a fact. If someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella, that would be circumstantial evidence from which you could conclude that it was raining.

It is your job to decide how much weight to give the direct and circumstantial evidence. The law makes no distinction between the weight that you should give to either one, nor does it say that one is any better evidence than the other. You should consider all the evidence, both direct and circumstantial, and give it whatever weight you believe it deserves.

### **1.5 CONSIDERATION OF EVIDENCE - AGREED**

You should use your common sense in weighing the evidence. Consider it in light of your everyday experience with people and events, and give it whatever weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.



## **1.6 STATEMENTS OF COUNSEL – AGREED**

A further word about statements of counsel and arguments of counsel. The attorneys' statements and arguments are not evidence. Instead, their statements and arguments are intended to help you review the evidence presented. If you remember the evidence differently from the attorneys, you should rely on your own recollection.

## **1.7 CREDIBILITY OF WITNESSES – AGREED IN PART**

**[Idenix proposal: You are the sole judges of each witness's credibility. You may believe everything a witness says, or part of it, or none of it. You should consider each witness's means of knowledge; strength of memory; how reasonable or unreasonable the testimony is in light of all of the evidence; whether it is consistent or inconsistent; whether it has been contradicted; the witness's biases, prejudices or interests; the witness's manner or demeanor on the witness stand; and any other factors that, according to the evidence, could affect the credibility of the testimony.]**

**[Gilead proposal: You are the sole judges of each witness's credibility. You should consider each witness's means of knowledge; strength of memory; opportunity to observe; how reasonable or unreasonable the testimony is; whether it is consistent or inconsistent; whether it has been contradicted; the witness's biases, prejudices, or interests; the witnesses' manner or demeanor on the witness stand; and all circumstances that, according to the evidence, could affect the credibility of the testimony.]**

In determining the weight to give to the testimony of a witness, you should ask yourself whether there is evidence tending to prove that the witness testified falsely about some important fact, or whether there was evidence that at some other time the witness said or did something, or failed to say or do something, that was different from the testimony he or she gave at the trial

**[Idenix proposal: in person or by deposition testimony played by video or read to you].**

You have the right to distrust such witness's testimony and you may reject all or some of the testimony of that witness or give it such credibility as you may think it deserves.

You should remember that a simple mistake by a witness does not necessarily mean that the witness was not telling the truth. People may tend to forget some things or remember other things inaccurately. If a witness has made a misstatement, you must consider whether it was an

innocent lapse of memory or an intentional falsehood, and that may depend upon whether it concerns an important fact or an unimportant detail.

### **1.8 NUMBER OF WITNESSES – AGREED**

One more point about the witnesses. Sometimes jurors wonder if the number of witnesses who testified makes any difference.

Do not make any decisions based only on the number of witnesses who testified. What is more important is how believable the witnesses were, and how much weight you think their testimony deserves. Concentrate on that, not the numbers.

## **1.9 EXPERT WITNESSES – AGREED**

Expert testimony is testimony from a person who has a special skill or knowledge in some science, profession or business. This skill or knowledge is not common to the average person but has been acquired by the expert through special study or experience.

In weighing expert testimony, you may consider the expert's qualifications, the reasons for the expert's opinions and the reliability of the information supporting the expert's opinions, as well as the factors I have previously mentioned for weighing testimony of any other witness. Expert testimony should receive whatever weight and credit you think appropriate, given all the other evidence in the case. You are free to accept or reject the testimony of experts, just as with any other witness.

### **1.10 DEPOSITION TESTIMONY – AGREED**

During the trial, certain testimony was presented to you by the reading of a deposition transcript or the playing of video excerpts from a deposition. If played by video, the deposition testimony may have been edited or cut to exclude irrelevant testimony. You should not attribute any significance to the fact that deposition videos may appear to have been edited.

Deposition testimony is entitled to the same consideration you would give it had the witness testified in person here in the courtroom.

**1.11 RULE 30(b)(6) DEPOSITION TESTIMONY – AGREED**

In this trial, there were certain witnesses identified as “Rule 30(b)(6) witnesses” for the parties. These Rule 30(b)(6) witnesses were designated to speak on certain topics on behalf of the entities which designated them as Rule 30(b)(6) witnesses. These witnesses include Dr. Michael Otto (designated by Gilead), Joseph Duffy (designated by Merck), and [NAME] (designated by [PARTY]). Rule 30(b)(6) witnesses are required to testify about information known or reasonably available to the designating entity related to those particular topics. For answers within the designated topics, the entity is bound by the answers provided by its Rule 30(b)(6) witness.

### **1.12 DEMONSTRATIVE EXHIBITS – AGREED IN PART**

During the course of the trial, you have seen many exhibits. Many of these exhibits were admitted as evidence. You will have these admitted exhibits in the jury room for your deliberations. **[Idenix proposal: During the course of this case, you have seen some exhibits (including charts or animations) that the parties used to help illustrate the testimony of various witnesses. These illustrative exhibits, also called “demonstrative exhibits,” may not have been offered and admitted as evidence in this case. If they have not been admitted, they should not be considered as evidence and you will not have them in the jury room with you.] [Gilead proposal: The remainder of the exhibits (including charts and animations) were offered to help illustrate the testimony of the various witnesses. These illustrative exhibits, called “demonstrative exhibits,” have not been admitted, are not evidence, and should not be considered as evidence. Rather, it is the underlying testimony of the witness that you heard when you saw the demonstrative exhibits that is the evidence in this case.]** Rather, it is the underlying testimony of the witness that you heard when you saw the demonstrative exhibits that is the evidence in this case.

**[Idenix proposal: In some instances, certain charts and summaries may have been received into evidence to illustrate information brought out in the trial. You may use these charts and summaries as evidence, even though the underlying documents and records are not here. You should give them only such weight as you think they deserve.**

**[Idenix Source: Final Jury Instructions, *Greatbatch Ltd. v. AVX Corporation, et al.*, 13-723-LPS (January 25, 2016).]**



### **1.13 BURDENS OF PROOF**

#### **IDENIX PROPOSAL**<sup>1</sup>

In any legal action, facts must be proven by a required weight of the evidence, known as the “burden of proof.” In a patent case such as this one, there are two different burdens of proof that you will apply. The first is called “preponderance of the evidence.” The second is called “clear and convincing evidence.”

In this case, infringement of the ‘597 patent is not an issue you are deciding in this case and Idenix is not required to prove infringement at this trial. Instead, you are to assume that Gilead infringes the ‘597 patent. You must decide whether Idenix has proven that Gilead’s infringement of any valid claim of the ‘597 patent was willful by what is called a preponderance of the evidence. That means Idenix must produce evidence that, considered in the light of all the facts, leads you to believe that what Idenix alleges is more likely true than not true. To put it differently, if you were to put the evidence of Idenix and Gilead concerning willful infringement on opposite sides of a scale, the evidence supporting Idenix’s allegations would have to make the scale tip somewhat toward Idenix’s side for you to issue a verdict in favor of Idenix on the issue of willful infringement. If the scale should remain equally balanced or tip in favor of Gilead, your verdict must be for Gilead on the issue of willful infringement.

Gilead also alleges that the asserted claims of the ‘597 patent are invalid, and Idenix contests that allegation. A patent is presumed to be valid under the U.S. patent laws. Accordingly, Gilead has the burden of proving by clear and convincing evidence that each asserted claim is invalid. Clear and convincing evidence is evidence that produces an abiding

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<sup>1</sup> Idenix maintains its objections to the Court’s ruling on infringement instructions but recognizes that the Court has ruled on this issue and thus limits these proposed instructions to comply with the Court’s ruling. *See* D.I. 485.

conviction that the truth of a factual contention is highly probable. Proof by clear and convincing evidence is thus a higher burden than proof by a preponderance of the evidence. In this case, you have heard evidence that the U.S. Patent and Trademark Office evaluated a prior patent that Gilead asserts for invalidity in this case. You may consider that fact when determining whether an invalidity defense has been proved by clear and convincing evidence.

Those of you familiar with criminal cases will have heard of “proof beyond a reasonable doubt.” That burden is higher than those that apply in this case, and it does not apply in a civil case like this one. Therefore, you should put it out of your mind in considering whether or not either party has met its burden of proof.

Idenix must also prove by a preponderance of the evidence the amount of damages that is adequate to compensate Idenix for Gilead’s infringement. I will give you more detailed instructions on damages later.

[Source: *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 111 (2011); D.I. 487 (Preliminary Jury Instruction No. 8); Final Jury Instructions, *Greatbatch Ltd. v. AVX Corporation, et al.*, 13-723-LPS (January 25, 2016).]

### **GILEAD PROPOSAL**

This is a civil case in which Gilead contends that Idenix’s ’597 patent is invalid.

A party challenging the validity of a patent has the burden of proving by clear and convincing evidence that the patent is invalid. Clear and convincing evidence is evidence that produces an abiding conviction that the truth of a factual contention is highly probable. In this case, you have heard evidence that the U.S. Patent and Trademark Office had no opportunity to evaluate before granting Idenix the ’597 patent. You may consider that fact when determining whether an invalidity defense has been proved by clear and convincing evidence.

Some of you may have heard the phrase “proof beyond a reasonable doubt.” That burden of proof applies only in criminal cases and has nothing to do with a civil case like this one. You should therefore not consider it in this case.

**Authority:** *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2251 (2011).]

#### **1.14 USE OF NOTES – AGREED**

You may use notes taken during trial to assist your memory. However, as I instructed you at the beginning of the case, you should use caution in consulting your notes. There is generally a tendency I think to attach undue importance to matters which one has written down. Some testimony which is considered unimportant at the time presented, and thus not written down, takes on greater importance later in the trial in light of all the evidence presented. Therefore, your notes are only a tool to aid your own individual memory, and you should not compare notes with other jurors in determining the content of any testimony or in evaluating the importance of any evidence. Your notes are not evidence, and are by no means a complete outline of the proceedings or a list of the highlights of the trial.

Above all, your memory should be the greatest asset when it comes time to deliberate and render a decision in this case.

[Source: D.I. 487 (Preliminary Jury Instruction No. 8); Final Jury Instructions, *Greatbatch Ltd. v. AVX Corporation, et al.*, 13-723-LPS (January 25, 2016).]

## **2. THE PARTIES AND THEIR CONTENTIONS**

### **2.1 THE PARTIES – AGREED IN PART**

I will now review for you the parties in this action, and the positions of the parties that you will have to consider in reaching your verdict.

#### **IDENIX PROPOSAL**

As I previously told you, the plaintiffs in this case are Idenix Pharmaceuticals LLC and Universita Degli Studi di Cagliari. I will refer to the plaintiffs collectively as “Idenix.” The defendant in this case is Gilead Sciences Inc., which I will refer to as “Gilead.”

#### **GILEAD PROPOSAL**

The plaintiffs in this case are Idenix Pharmaceuticals LLC and Universita Degli Studi di Cagliari. I will refer to the plaintiffs collectively as “Idenix.” The defendants in this case are Gilead Sciences Inc. and Gilead Pharmasset LLC, which I will refer to as “Gilead.”

## **2.2 PLAINTIFFS' CONTENTIONS – IDENIX PROPOSAL**

The Idenix patent in this case is United States Patent No. 7,608,597, often referred to by the lawyers and witnesses as the '597 patent. The patent has also been referred to as the "asserted patent" or the "patent-in-suit." The asserted claims are Claims 1, 2, 4-7, 9-10, 16, 19, 23 and 28-31 of the '597 patent. The inventors of the '597 patent are Dr. Jean-Pierre Sommadossi and Dr. Paolo La Colla. Dr. Sommadossi assigned his patent rights to Idenix, and Dr. La Colla assigned his rights to the University.

You are to assume that Gilead infringes the '597 patent. Idenix is not required to prove infringement. Idenix alleges that Gilead's infringement of Claims 1, 2, 4-7, 9-10, 16, 19, 23 and 28-31 of the '597 patent has been and continues to be willful. Idenix also contends that Gilead owes Idenix damages to compensate for Gilead's infringement in the form of a reasonable royalty.

I will explain further each of these contentions in a few moments.

[Sources: Final Jury Instructions, *Greatbatch Ltd. v. AVX Corporation, et al.*, 13-723-LPS (January 25, 2016); Final Jury Instructions, *Helios Software, LLC et al. v. Spectorsoft Corp.*, 12-081-LPS (June 19, 2015).]

### **2.3 DEFENDANT'S CONTENTIONS – AGREED**

Gilead contends that the asserted claims of the '597 patent are invalid. Gilead also denies that its conduct is willful.

I will explain further these contentions in a few moments.

## **2.4 SUMMARY OF THE PATENT ISSUES – IDENIX PROPOSAL<sup>2</sup>**

I will now summarize the patent issues that you must decide and for which I will provide instructions to guide your deliberations.

Infringement of the ‘597 patent is not an issue you are deciding in this case and Idenix is not required to prove infringement at this trial. Instead, you are to assume that Gilead infringes the ‘597 patent since use of SOVALDI® and HARVONI® in accordance with their respective labels results in use of the methods defined by the asserted claims of the ‘597 patent under the Court’s claim construction.

Here are the issues you must decide:

1. Whether Idenix has proven by a preponderance of the evidence that Gilead’s assumed infringement has been and is willful.
2. Whether Gilead has proven by clear and convincing evidence that one or more of the asserted claims of the ‘597 patent are invalid due to lack of written description, lack of enablement, or prior invention by Bohdan Wolanski or David Olsen. For some of these issues, you will first need to make one or more preliminary determinations that I will explain to you shortly. Each asserted claim is evaluated separately.
3. If you do not find each and every one of the asserted claims invalid by clear and convincing evidence, then you must determine the amount of money damages to be awarded to Idenix. Idenix has the burden to establish the amount of its damages by a preponderance of the evidence.

[Source: Final Jury Instructions, *Greatbatch Ltd. v. AVX Corporation, et al.*, 13-723-LPS (January 25, 2016).]

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<sup>2</sup> Gilead objects to this instruction being given.



**3. PATENT LAWS – AGREED**

At the beginning of the trial, I gave you some general information about patents and the patent system and a brief overview of the patent laws relevant to this case. I will now give you more detailed instruction about the patent laws that specifically relate to this case.

#### 4. THE PATENT CLAIMS

##### 4.1 GENERALLY – AGREED IN PART

Before you can decide many of the issues in this case, you will need to understand the role of patent “claims.”

The patent claims are the numbered paragraphs at the end of each patent. The claims are important because it is the words of the claims that define what a patent covers. **[Idenix proposal: The claims are intended to define, in words, the boundaries of the invention that constitute the patent owner’s property rights. Infringement is an act of trespassing on those rights. Only the claims of a patent can be infringed. Neither the specification, which is the written description of the invention, nor the drawings of a patent can be infringed. A preferred embodiment is not necessarily the full scope of the patent claim. The figures and text] [Gilead proposal: The text] in the rest of the patent [Idenix proposal: provide] [Gilead proposal: provides] a description and/or examples of the invention and [Idenix proposal: provide] [Gilead proposal: provides] a context for the claims, but it is the claims that define the breadth of the patent’s coverage. **[Idenix proposal: Each of the asserted claims must be considered individually.]****

Each claim of a patent effectively acts as if it were a separate patent, and each claim may cover more or less than another claim.

**[Gilead proposal: You will first need to understand what each claim covers in order to decide whether or not the claim is invalid.]**

The law says that it is my role to define the terms of the claims and it is your role to apply my definitions to the issues that you are asked to decide in this case. Therefore, as I mentioned to you at the start of the case, I have determined the meaning of certain terms in the claims and I will provide to you my definitions of those claim terms. You must accept

**my definitions of these words in the claims as being correct. It is your job to take these definitions and apply them to the validity issues that you are deciding.]**

[Idenix Sources: Final Jury Instructions, *Greatbatch Ltd. v. AVX Corporation, et al.*, 13-723-LPS (January 25, 2016); Final Jury Instructions, *Helios Software, LLC et al. v. Spectorsoft Corp.*, 12-081-LPS (June 19, 2015).]

#### 4.2 CONSTRUCTION OF THE CLAIMS – AGREED

It is the Court's duty under the law to define what the patent claims mean. As I instructed you at the beginning of the case, I have made my determinations, and I will now instruct you on the meaning of claim terms. You must apply the meaning that I give in each patent claim to decide if the claim is invalid. You must ignore any different definitions used by the witnesses or the attorneys. For any words in the claim for which I have not provided you with a definition, you should apply the plain and ordinary meaning to a person of ordinary skill in the art.

It may be helpful to refer to the copy of the '597 patent that you have been given as I discuss the claims at issue here. The claims of the patent are toward the end of the patent.

You are advised that the following definitions for the following terms must be applied:

<b>Claim Term</b>	<b>Court's Construction</b>
Method for the treatment of a Hepatitis C virus infection	Plain and ordinary meaning
Administering	Making available
Effective amount	An amount [of the claimed ribofuranosyl nucleoside] that is effective to treat HCV
Nucleoside	A compound comprising a base linked to a sugar
$\beta$ -D-2'-methyl-ribofuranosyl nucleoside	A $\beta$ -D- nucleoside that includes a five member sugar ring with a methyl group in the 2' up position and non-hydrogen substituents at the 2' down and 3' down positions

#### **4.3 INDEPENDENT AND DEPENDENT CLAIMS – AGREED**

There are two different types of claims in the patent. The first type is called an “independent claim.” An independent claim does not refer to any other claim of the patent. An independent claim is read separately to determine its scope.

On the other hand, a “dependent claim” refers to and depends upon at least one other claim in the patent and thus incorporates whatever that other claim says. Accordingly, to determine what a dependent claim covers, you must read both the dependent claim and the claim or claims to which it refers. For example, claim 1 of the '597 patent is an independent claim. You know this because it mentions no other claims. Accordingly, the words of claim 1 of the '597 patent are read by themselves in order to determine what claim 1 covers. Claim 2 of the '597 patent, on the other hand, is a dependent claim. You know this because it refers to independent claim 1. Accordingly, the words of claims 1 and 2 are read together in order to determine what claim 2 of the '597 patent covers.

#### **4.4 OPEN ENDED OR “COMPRISING” CLAIMS – IDENIX PROPOSAL**

The asserted claims all include the word “comprising.” The word “comprising” means “includes the following but not excluding others.” A claim that uses the word “comprising” is not limited to products or methods having only the elements that are recited in the claim, but also covers products and methods that have additional elements.

[Sources: Final Jury Instructions, *Greatbatch Ltd. v. AVX Corporation, et al.*, 13-723-LPS (January 25, 2016); Final Jury Instructions, *Helios Software, LLC et al. v. Spectorsoft Corp.*, 12-081-LPS (June 19, 2015).]

## **5. PATENT INFRINGEMENT – IDENIX PROPOSAL**

I will now instruct you on what it means to infringe a patent. The U.S. patent laws give the owner of a patent the right to keep others from making, using, selling, or offering to sell a patented product, or performing a patented method, within the United States during the term of the patent. Any person or business entity that performs the patented method in the United States during the term of the patent without the patent owner's permission infringes the patent, so long as the patent is not found to be invalid.

In this case, Gilead is assumed to infringe the '597 patent in two ways: (1) active inducement and (2) contributory infringement. These are both a form of "indirect infringement." Indirect infringement is different from direct infringement, which can occur unintentionally. Indirect infringement requires that the infringer know of, or is willfully blind to, the existence of the patent that is infringed.

A party induces infringement if it causes, urges, or encourages another to infringe a claim of the patent which it is aware of or to which it was willfully blind. Willful blindness exists where the party believes there is a high probability that its acts, if taken, would constitute infringement, but the party deliberately avoids confirming that belief. For example, Gilead induces infringement of the '597 patent by selling the accused SOVALDI® and HARVONI® products with instructions leading others to use the products in accordance with their labels which results in the use of the methods defined by the asserted claims of the '597 patent under the Court's claim construction.

Contributory infringement occurs when a party with knowledge of the patent sells a part, or a component, to another for use in a product or method that infringes a patent, the contributory infringer knows that the component was especially made to be used in a manner that infringes, and the component has no substantial non-infringing use.

[Sources: Final Jury Instructions, *Ateliers de la Haute-Garonne, et al. v. Broetje Automation-USA Inc., et al.*, 09-598-LPS (April 11, 2014); Final Jury Instructions, *Greatbatch Ltd. v. AVX Corporation, et al.*, 13-723-LPS (January 25, 2016); *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920 (2015); *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 765, 131 S. Ct. 2060, 2068 (2011).]



**6. EXEMPTION FROM INFRINGEMENT – IDENIX PROPOSAL<sup>3</sup>**

It is not infringement for a party to use a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs. In this case, Idenix could not seek damages for Gilead's infringement until the accused products were commercially available in the market.

[Source: 35 U.S.C. § 271(e)(1).]

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<sup>3</sup> Gilead objects to this instruction being given.

## 7. WILLFUL INFRINGEMENT

### **IDENIX PROPOSAL**

Idenix alleges that Gilead acted willfully. To prove willful infringement, Idenix must prove by a preponderance of the evidence that Gilead's conduct was reckless, willful, wanton, malicious, committed in bad faith, deliberate, consciously wrongful, flagrant, or—as it may be described—characteristic of a pirate. To determine whether Gilead acted willfully, consider all of the facts. These facts may include, but are not limited, to:

- whether or not Gilead acted in a manner consistent with the standards of commerce for its industry;
- whether or not Gilead intentionally copied a product of Idenix that is covered by the '597 patent, intentionally copied the '597 patent, or intentionally copied Idenix's ideas related to the '597 patent;
- whether or not Gilead reasonably believed that the patent was invalid;
- whether or not Gilead tried to cover up its infringement;
- whether Gilead reasonably believed that the patent was invalid;
- whether or not Gilead was willfully blind to its infringement;
- whether or not Gilead knew or had reason to know it was infringing; and
- Gilead's failure to obtain or rely on an opinion of counsel that it was not infringing the claims or that the claims are invalid.

[Sources: *Halo Elecs., Inc. v. Pulse Elecs.*, 136 S. Ct. 1923, 1932 (2016); *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317 (Fed. Cir. 2016); Federal Circuit Bar Association Model Instruction No. 3.10.]

**GILEAD PROPOSAL**<sup>4</sup> [proposed location: after invalidity instructions]

If you conclude that the '597 patent is not invalid, then you must determine whether Gilead willfully infringed the '597 patent.

To prove willful infringement, Idenix must prove by a preponderance of the evidence that Gilead had knowledge of the '597 patent and that Gilead's conduct was willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or characteristic of a pirate. Mere knowledge of the '597 patent is not sufficient.

You must base your verdict on the knowledge and actions of Gilead from December 6, 2013 to present, and you are not permitted to consider any knowledge or actions by Gilead or Pharmasset that were before December 6, 2013.

In deciding whether Gilead's infringement was willful, you may consider whether Gilead acted in a manner consistent with the standards of commerce for its industry.

If you decide that there was willful infringement that decision should not affect any damage award you give in this case.

Authority: *Halo Elecs., Inc. v. Pulse Elecs.*, 136 S. Ct. 1923, 1932-33 (2016); *Gustafson, Inc. v. Intersystems Indus. Prods., Inc.*, 897 F.2d 508, 510 (Fed. Cir. 1990); *Am. Original Corp. v. Jenkins Food Corp.*, 774 F.2d 459, 465 (Fed. Cir. 1985); 35 U.S.C. § 298.

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<sup>4</sup> Gilead again preserves for appeal its objection to submitting the issue of willful infringement to the jury. Although Gilead acknowledges that existing Federal Circuit precedent envisions submission of willfulness to the jury, this is inconsistent with the relevant statute, 35 U.S.C. § 284, which directs that enhanced damages are to be decided by "the court," and Gilead thus preserves the right to ask the appellate courts to overrule that precedent. Gilead notes that this case is the quintessential example of why willfulness should not be submitted to a jury—Idenix has made irrelevant arguments about Pharmasset's alleged conduct before the '597 patent issued a centerpiece of its case to distract the jury from the merits of Gilead's invalidity defenses. Indeed, Idenix's opening statement was almost solely directed to characterizing this case as one "betrayal" and "theft," rather than about what the '597 patent actually discloses or enables.

## **8. INVALIDITY**

### **8.1 GENERALLY**

#### **IDENIX PROPOSAL**

The granting of a patent by the United States Patent and Trademark office carries with it the presumption that the patent is valid. The law presumes that the Patent and Trademark Office acted correctly in issuing the patent. Each of the asserted claims is presumed valid independently of the validity of each other claim. This presumption puts the burden on Gilead of proving invalidity by clear and convincing evidence on a claim-by-claim basis; that is, you must be left with an abiding conviction that the asserted claims of the '597 patent are invalid. This burden always remains with Gilead and never shifts to Idenix.

[Sources: Final Jury Instructions, *Tarkus Imaging, Inc. v. Adobe Sys., Inc.*, No. 10-063-LPS (June 27, 2012); *Microsoft Corp. v. i4i LP*, 564 U.S. 91, 110-11 (2011).]

#### **GILEAD PROPOSAL**

Even though the Patent Office examiner allowed the claims of a patent, you have the ultimate responsibility for deciding whether the claims of the patent are proven to be invalid.

For a patent to be valid, the subject matter claimed in the individual claims of the patent must be new, non-obvious, and the specification of the patent must be contain a sufficient written description of the claimed invention and must enable people to make the invention. A patent cannot take away from the right of anyone who wants to use what was already known or used by others, or what would have been obvious to those of skill in the art at the time the invention was made.

## **8.2 OTHER PATENTS – IDENIX PROPOSAL<sup>5</sup>**

In this case, you heard testimony and saw evidence about patents other than Idenix's '597 patent that may cover Gilead's SOVALDI® and HARVONI® products. More than one patent by the same or different owners can cover a product or its use. Often, multiple patents cover the same product or its use. The fact that Gilead has patents that may cover its SOVALDI® and HARVONI® products or their use does not mean that any of the asserted claims of the '597 patent are invalid.

[Source: Final Jury Instructions, *Gilead Sciences, Inc. v. Merck & Co. Inc., et al.*, 13-4057-BLF, D.I. 352 Special Instruction No. 40 (N.D. California, March 16, 2016).]

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<sup>5</sup> Gilead objects to this instruction being given.

### **8.3 LEVEL OF ORDINARY SKILL**

#### **IDENIX PROPOSAL**

Patent invalidity defenses are evaluated from the perspective of a hypothetical “person of ordinary skill in the art.” The hypothetical person of ordinary skill in the art is presumed to be aware of all the prior art at the time of the invention.

You are to determine the level of ordinary skill in the art to which the claimed invention pertains at the time the claimed invention was made. In deciding what the level of ordinary skill in the relevant field is, you should consider all the evidence introduced at trial, including but not limited to: the levels of education and experience of other persons actively working in the field. In this case, the level of ordinary skill in the art is high, for example, having a Ph.D. and at least two years of experience in the relevant field.

[Source: *Gilead Sciences, Inc. v. Merck & Co., Inc.*, No. 5:13-cv-04057, D.I. 352 Instruction No. 7.3 (N.D. Cal. Mar. 16, 2013).]

**GILEAD PROPOSAL:** See Gilead’s Proposed Instruction 8.14.2.

#### **8.4 WRITTEN DESCRIPTION**

##### **IDENIX PROPOSAL**

Gilead contends that the asserted claims of the '597 patent are invalid for lack of an adequate written description.

In deciding whether a specification satisfies this written description requirement, you must consider the description from the viewpoint of a person having ordinary skill in the field of technology of the patent when the application was filed. The written description requirement is satisfied if it would have reasonably conveyed to a person having ordinary skill reading the patent application as of its filing date that the inventor had possession of the full scope of the claimed invention, even though the description may not use the exact words found in the claims. No particular form of written description is required. The written description requirement may be satisfied by any combination of words, structures, figures, diagrams, formulas, experiments, data, etc., contained in the patent application. These are often called "blaze marks." The full scope of a claim or any particular requirement in a claim (at the time of the filing) need not be expressly disclosed in the patent application if a person having ordinary skill in the field of technology of the patent at the time of filing would have understood that the inventors had possession of the claimed invention when filing their patent application.

In the patent application process, the applicant may keep the originally filed claims, or expand, narrow or change the claims between the time the patent application is first filed and the time a patent is issued. An application may amend the claims or add new claims. This includes amendments to cover a competitor's product. The patent claim scope may even cover later developed modifications or improvements of the invention, whether or not they are covered by a subsequent patent or not. The written description requirement ensures that the issued claims are supported by the patent specification as a whole as originally filed.

A patent claim is not necessarily invalid for lack of written description just because it is broader than the specific examples disclosed. A pioneering invention may receive a broad patent when shown to have a broad scope. Simply because the description of the invention in the specification is narrower than that in the claim does not mean there has been a failure to fulfill the written description requirement. The written description requirement only requires that the specification reasonably convey to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. The written description requirement does not require the specification to have specifically disclosed the accused technology, product, or method. The written description requirement also does not require that the description in the specification include every conceivable and possible future embodiment, including later invented embodiments, of the claimed invention.

The '597 patent relates to methods of using chemical compounds. Patents can disclose chemical compounds as single compounds or as classes of compound, for example, by using words or by using a general structural formula. For genus (or class of compound) claims, every species (or specific example of the class) in a claimed genus need not be described to satisfy the written description requirement. Where a claim has been construed to cover a chemical compound, the specification does not need to disclose how to prepare a particular form among the possible permutations of that compound. The specification may provide a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus. There is no bright-line rule governing the number of species that must be disclosed to describe a genus claim, as this number changes with each invention and progress in the field.



[Source: Final Jury Instructions, *Masimo Corp. v. Philips Electronics North America Corp., et al.*, 09-80-LPS (September 30, 2014); *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977); *In re Koller*, 613 F.2d 819 (C.C.P.A. 1980); *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc); *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997); *Gilead Sciences, Inc. v. Merck & Co., Inc.*, No. 5:13-cv-04057, D.I. 352 Instruction No. 23 (N.D. Cal. Mar. 16, 2013); *Pfizer v. Teva Pharm. USA, Inc.*, 555 F. App'x 961, 967 (Fed. Cir. 2014); *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1359 (Fed. Cir. 2010); *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967).]

### **GILEAD PROPOSAL**

A patent must include an adequate written description of the full scope of the claimed invention. The purpose of the written description requirement is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.

Gilead contends that the asserted claims of Idenix's '597 patent are invalid because the specification of the '597 patent does not contain an adequate written description of the invention that is claimed in that patent.

To succeed, Gilead must show by clear and convincing evidence that the specification fails to meet the law's requirements for written description of the invention. In the patent application process, the applicant may keep the originally filed claims, or change the claims between the time the patent application is first filed and the time a patent is issued. An applicant may amend the claims or add new claims. These changes may narrow or broaden the scope of the claims, so long as any changes are supported by the original specification. The full scope of the claims that are granted must be described by the disclosure of the original patent application. The written description requirement ensures that the issued claims correspond to the scope of the written description that was provided in the original application and prevents someone from writing claims that are broader than what is actually described in the originally filed application.

In deciding whether the patent satisfies this written description requirement, you must consider the description from the viewpoint of a person having ordinary skill in the field of technology of the patent when the application was filed. The written description requirement may be satisfied by any combination of the words, structures, figures, diagrams, formulas, etc., contained in the patent application but must describe the full scope of the asserted claims. The written description requirement is satisfied if a person having ordinary skill reading the original patent application would have recognized, within the four corners of the patent application as filed, that it describes the full scope of the claimed invention as it is finally claimed in the issued patent and that the inventor actually invented the full scope of what is claimed and possessed that full scope by the filing date of the original application. If the claim covers technology that had not been invented by the time the patent was filed, the patent cannot show possession of that technology, and the claim is invalid for lack of written description.

Idenix's asserted claims, as construed by the Court, cover only methods of treatment of Hepatitis C that are actually effective, using compounds that include a 2'-methyl (up) but not hydrogen at 2' down. To provide adequate written description for claims covering this set of compounds, it is not enough if the '597 patent discloses the use of some compounds that meet these criteria. Instead, the specification must provide "blaze marks" that would direct a person having ordinary skill in the field of technology to the full set of compounds that are covered by the claims and distinguish the compounds that are recited in the claims from all other compounds described in the patent. The requirement for "blaze marks" is not met by a mere list of options that does not indicate which compounds meet the criteria and are thus covered by the claims and which compounds are not. One cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written

description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.

**Authority:** Federal Circuit Bar Association Model Patent Jury Instruction 4.2(a); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (*en banc*); *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299 (Fed. Cir. 2008); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565 (Fed. Cir.1997); *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353 (Fed. Cir. 2011); *Fujikawa v. Wattanasin*, 93 F.3d 1559 (Fed. Cir. 1996); *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967); *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326 (Fed. Cir. 2000); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004).

## **8.5 ENABLEMENT**

### **IDENIX PROPOSAL**

Gilead contends that the asserted claims of the '597 patent are invalid for lack of an enabling disclosure in the specification. Gilead has the burden of proving non-enablement of each asserted claim by clear and convincing evidence.

The patent laws require that the patent's specification be sufficiently detailed to enable those skilled in the art to make and use the claimed invention without undue experimentation. This is known as the "enablement" requirement. The purpose of this requirement is to ensure that the public, in exchange for the patent rights given to the inventor, obtains from the inventor a sufficient disclosure of how to carry out the claimed invention.

To meet this requirement, the patent disclosure must allow a person of ordinary skill in the art to practice the invention without undue experimentation. Moreover, the fact that some experimentation may be required for a skilled person to practice the claimed invention does not mean that the specification is not enabling. A specification is enabling so long as undue experimentation is not needed.

Because descriptions in patents are addressed to those skilled in the field of art to which the invention pertains, an applicant for a patent need not expressly include information that is commonly understood by persons skilled in the art. Similarly, a patent need not contain a working example of the claimed invention so long as the patent discloses enough information to enable a person of ordinary skill in the art to practice the claimed invention. Also, enablement does not require that the specification enable the accused product or later invented products. Enablement does not require the inventor to foresee every means of implementing an invention.

Some amount of experimentation to make and use the invention is allowable. In deciding whether a person having ordinary skill would have to experiment unduly in order to make and use the invention, you may consider several factors:

- 1) the quantity of experimentation necessary;
- 2) how routine any necessary experimentation is in the field;
- 3) whether the patent discloses specific working examples of the claimed invention;
- 4) the amount of guidance presented in the patent;
- 5) the nature and predictability of the field;
- 6) the level of ordinary skill in the field; and
- 7) the scope of the claimed invention.

No one or more of these factors is alone dispositive. Rather, you must make your decision whether or not the degree of experimentation required is undue based upon all of the evidence presented to you. You should weigh these factors and determine whether or not, in the context of the claimed invention at issue and the state of the art at the time of the application, a person having ordinary skill would need to experiment unduly to make and use the full scope of the claimed invention.

The “how to use” prong of the enablement requirement is also called the utility requirement. An invention is useful if the specification disclose a practical utility for the invention. If the specification contains a teaching of the manner of using the invention in terms that correspond to the claims, that disclosure must be taken as compliance with the “how to use” prong. A patentee does not need to obtain FDA approval for a product covered by the invention to satisfy the utility or “how to use” requirements included in the enablement analysis.

[Source: Final Jury Instructions, *Masimo Corp. v. Philips Electronics North America Corp., et al.*, 09-80-LPS (September 30, 2014); *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977); D.I. \_\_\_\_

(Transcript of July 26, 2016 Hearing on Motions for Summary Judgment and *Daubert* Motions) at 115-16; *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995); *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005).]

### **GILEAD PROPOSAL**

A patent specification must contain a sufficiently full and clear description of how to make and use the full scope of the claimed invention. This is known as the “enablement” requirement, and it is designed to prevent both inadequate disclosure of an invention and overbroad claiming that might otherwise attempt to cover more than was actually invented.

Gilead contends that the asserted claims of the ’597 patent are invalid because they are not enabled. To succeed, Gilead must show by clear and convincing evidence that the ’597 patent does not contain a sufficiently full and clear description of the claimed invention, which, as construed, cover methods of treatment of Hepatitis C that are actually effective, using compounds that include a 2’-methyl (up) but not hydrogen at 2’ down. In order to be enabling, the patent must permit persons having ordinary skill in the field of technology of the patent to make and use the full scope of the claimed invention at the time of original filing without having to conduct undue experimentation. However, some amount of experimentation to make and use the invention is allowable. If an inventor attempts but fails to make an embodiment of the patented invention, that is strong evidence that the patent specification lacks enablement.

In deciding whether a person having ordinary skill would have to experiment unduly in order to make and use the invention, you may consider several factors:

- (1) the time and cost of any necessary experimentation;
- (2) how routine any necessary experimentation is in the relevant field;
- (3) whether the patent discloses specific working examples of the claimed invention;
- (4) the amount of guidance presented in the patent
- (5) the nature and predictability of the field;

(6) the level of ordinary skill; and

(7) the scope of the claimed invention.

No one or more of these factors is alone dispositive. Rather, you must make your decision whether or not the degree of experimentation required is undue based upon all of the evidence presented to you with regard to all of the factors above. You should weigh these factors and determine whether or not, in the context of this invention and the state of the art at the time of the original application, a person having ordinary skill would need to experiment unduly to make and use the full scope of the claimed invention.

**Authority:** Federal Circuit Bar Association Model Patent Jury Instruction 4.2(b); *MagSil Corp. v. Hitachi Global Storage Technologies, Inc.*, 687 F.3d 1377 (Fed. Cir. 2014); *ALZA Corp. v. Andrx Pharms., LLC*, 660 F.3d 935, 942 (Fed. Cir. 2010); *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1319 (Fed. Cir. 2007).

## **8.6 GILEAD’S ANTICIPATION CONTENTIONS – IDENIX PROPOSAL**

A patent claim is invalid if the claimed invention is not new. For a method claim to be invalid because it is not new, all of its requirements must have been present in a single method that predates the claimed invention. If a patent claim is not new, we say that it was “anticipated.” Anticipation must be proved on a claim-by-claim basis. Gilead bears the burden of proving anticipation by clear and convincing evidence for each and every asserted claim of the ‘597 patent.

Gilead contends that the asserted claims of the ‘597 patent are anticipated on three grounds:

1. Gilead contends an alleged prior invention by Bohdan Wolanski in 1998.
2. Based upon an assertion that Idenix is not entitled to its May 23, 2000 priority date, which I will instruct on shortly, Gilead contends anticipation by an alleged prior invention by David Olsen in September 2000.
3. Based upon an assertion that Idenix is not entitled to its May 23, 2000 priority date, Gilead contends anticipation by U.S. Patent No. 7,202,224 owned by Merck. You may have heard this patent referred to as the Merck patent or the ‘224 patent. Gilead claims that the Merck patent has a priority date of January 22, 2001.

[Source: 35 U.S.C. §§ 102(e), (g); Final Jury Instructions, *Fairchild Semiconductor Corp., et al. v. Power Integrations, Inc.*, 12-540-LPS (June 4, 2015); Final Jury Instructions, *Greatbatch Ltd. v. AVX Corporation, et al.*, 13-723-LPS (January 25, 2016); *Fleming v. Escort Inc.*, No. 09-105, D.I. 305 (D. Idaho July 3, 2012).]



**8.7 PRIOR INVENTION – IDENIX PROPOSAL [PROPOSED INSTRUCTIONS 8.7 THROUGH 8.10 ARE IDENIX PROPOSALS; PROPOSED INSTRUCTIONS 8.11 THROUGH 8.14.4 ARE GILEAD PROPOSALS EXCEPT IDENIX INCLUDES A COUNTER-PROPOSAL FOR 8.14]**

As just mentioned, Gilead contends that the asserted claims of the ‘597 patent were anticipated because the invention defined in the claims was invented by another person, either Bohdan Wolanski in 1998 or David Olsen in 2000, before Dr. Sommadossi and Dr. La Colla invented their invention.

A patent claim is invalid if the invention defined by that claim was invented by another person in the United States before it was invented by the patentee, and that other person did not abandon, suppress, or conceal the invention.

Only a person may be an inventor. A corporation cannot be an inventor. Invention requires conception and reduction to practice. Conception occurs when the inventor has a specific, settled idea, a particular solution to the problem at hand. The date of conception is the date the inventor first appreciated the fact of what he or she made, which requires that the inventor actually understood his or her creation to have the features that comprise the inventive subject matter. It is not enough that a party adduce evidence that objective test results comport with an inventor’s testimony concerning his or her state of mind. Rather, there must also be objective evidence corroborating that the alleged inventor timely interpreted or evaluated the results, and understood them to show the existence of the invention.

Reduction to practice can be “actual” or “constructive.” In order to establish actual reduction to practice, the prior inventor must have (1) constructed an embodiment or performed a method that met all the claim limitations and (2) determined that the invention would work for its intended purpose. An accidental, unappreciated or unrecognized actual reduction to practice does not constitute a true reduction to practice for the purposes of determining priority of

invention or anticipation. A constructive reduction to practice occurs when a patent application describing and enabling the claimed invention is filed.

Further, an invention loses its status as an invention if it was abandoned, suppressed, or concealed. Absent a satisfactory explanation for any delay, a conception and reduction to practice of an alleged prior invention is deemed abandoned, suppressed or concealed if, within a reasonable time after completion, no steps are taken to make the invention publicly known. Abandonment, suppression, or concealment can be inferred from an unreasonable delay between the actual reduction to practice and the filing of a patent application. Gilead must overcome any evidence that a given alleged inventor abandoned, suppressed, or concealed his or her invention with clear and convincing evidence to the contrary.

If you find that Gilead failed to prove by clear and convincing evidence that Dr. Wolanski and Dr. Olsen conceived and reduced to practice all of the requirements of the asserted claims, and/or that Gilead failed to prove that Dr. Wolanski and Dr. Olsen did not abandon, suppress, or conceal any alleged prior invention, you must also find that the asserted claims are not anticipated by prior invention. If, however, you do not make these findings, priority of invention is a dispute you may need to decide in this case. I will now provide instructions on priority.

[Sources: 35 U.S.C. § 102(g)(2); 35 U.S.C. §§ 115-118; *Beech Aircraft Corp. v. EDO Corp.*, 990 F.2d 1237, 1248 (Fed. Cir. 1993); *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008); *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1036-37 (Fed. Cir. 2001); *Price v. Symsek*, 988 F.2d 1187 (Fed. Cir. 1993); *Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303 (Fed. Cir. 2011); *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052 (Fed. Cir. 2005); *Teva Pharm. Indus. v. AstraZeneca Pharm. LP*, 661 F.3d 1378 (Fed. Cir. 2011); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986); *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316 (Fed. Cir. 2001); *Stamicarbon BV v. Sepracor, Inc.*, Civil Action No. 97-8-GMS (D. Del. Mar. 12, 2001); *Fleming v. Escort Inc.*, 774 F.3d 1371 (Fed. Cir. 2014); *Lutzker v. Plet*, 843 F.2d 1364 (Fed. Cir. 1988); *Fleming v. Escort Inc.*, No. 09-105, D.I. 305 (D. Idaho July 3, 2012); *Solvay, S.A. v. Honeywell Specialty Materials LLC*, No. 06-557-SLR, D.I. 365 (D. Del. Sept. 28, 2011).]

## 8.8 IDENIX'S PRIORITY DATE – IDENIX PROPOSAL

The date of filing of Idenix's provisional application is May 23, 2000. Gilead claims that Idenix is not entitled to that date in a priority date. If you find that Gilead has failed to prove by clear and convincing evidence that Idenix is not entitled to a priority date of May 23, 2000, you must also find that Gilead has failed to prove anticipation by alleged prior invention or prior patent. If you find that Idenix is entitled to a later priority date of May 23, 2001, you must determine the priority dispute between the '597 patent and the alleged prior invention by Dr. Olsen in September 2000, and you will also determine a priority dispute between the '597 patent and the Merck's '224 patent with a filing date of January 22, 2001.

[Sources: 35 U.S.C. § 102(g); *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008); *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1036-37 (Fed. Cir. 2001); *Price v. Symsek*, 988 F.2d 1187 (Fed. Cir. 1993); *Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303 (Fed. Cir. 2011); *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052 (Fed. Cir. 2005); *Teva Pharm. Indus. v. AstraZeneca Pharm. LP*, 661 F.3d 1378 (Fed. Cir. 2011); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986); *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316 (Fed. Cir. 2001); *Stamicarbon BV v. Sepracor, Inc.*, Civil Action No. 97-8-GMS (D. Del. Mar. 12, 2001); *Fleming v. Escort Inc.*, 774 F.3d 1371 (Fed. Cir. 2014); *Lutzker v. Plet*, 843 F.2d 1364 (Fed. Cir. 1988); *Fleming v. Escort Inc.*, No. 09-105, D.I. 305 (D. Idaho July 3, 2012).]

## **8.9 PRIORITY – IDENIX PROPOSAL**

I will now instruct you on determining a priority dispute. The first inventor to reduce an invention to practice is entitled to priority of invention unless the other inventor was first to conceive the invention and reasonably diligent in reducing the invention to practice. For example, if a party (PARTY A) was the first to reduce to practice an invention, that party (PARTY A) is not entitled to priority of invention if another party (PARTY B) was first to conceive of that invention, even if PARTY B reduced that invention to practice later than PARTY A, so long as PARTY B was diligent in reducing its invention to practice from a time prior to PARTY A's actual or constructive reduction to practice and its own (PARTY B's) actual or constructive reduction to practice. Evidence of constant effort is not required to establish reasonable diligence. Nor does a party have to take the most expeditious course to the reduction to practice, so long as the party's efforts are reasonably diligent under the circumstances. Thus, the question is whether the inventors pursued their goal in a reasonable fashion. In other words, if they were doing the things reasonably necessary to reduce the idea to practice, then they were diligent even if they did not actually work on the invention each day. The law requires only reasonable and not heroic diligence. In that regard, diligence must be considered in light of all the circumstances and the question to answer is whether the inventor was pursuing his goal in a reasonably continuous fashion.

For Gilead to prove anticipation by prior invention by Dr. Olsen, Gilead must prove by clear and convincing evidence either that, before Dr. Sommadossi and Dr. La Colla invented their claimed invention of the asserted claims of the '597 patent, Dr. Olsen reduced to practice a method that included all of the elements of the asserted claims of the '597 patent, or that Dr. Olsen was first to conceive the invention and that he exercised reasonable diligence in later reducing the invention to practice. In addition, Gilead must show that Dr. Olsen's alleged

invention was sufficiently developed that one skilled in the art would have recognized that it would work for its intended purposes. Gilead contends that Dr. Olsen conceived and reduced to practice his alleged invention in September 2000.

For Gilead to prove anticipation by Merck's '224 patent, Gilead must prove by clear and convincing evidence that Dr. Sommadossi and Dr. La Colla did not invent their claimed invention of the asserted claims of the '597 patent until after the January 22, 2001 filing date of the Merck '224 patent.

[Sources: 35 U.S.C. § 102(g); *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008); *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1036-37 (Fed. Cir. 2001); *Price v. Symsek*, 988 F.2d 1187 (Fed. Cir. 1993); *Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303 (Fed. Cir. 2011); *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052 (Fed. Cir. 2005); *Teva Pharm. Indus. v. AstraZeneca Pharm. LP*, 661 F.3d 1378 (Fed. Cir. 2011); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986); *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316 (Fed. Cir. 2001); *Stamicarbon BV v. Sepracor, Inc.*, Civil Action No. 97-8-GMS (D. Del. Mar. 12, 2001); *Fleming v. Escort Inc.*, 774 F.3d 1371 (Fed. Cir. 2014); *Lutzker v. Plet*, 843 F.2d 1364 (Fed. Cir. 1988); *Fleming v. Escort Inc.*, No. 09-105, D.I. 305 (D. Idaho July 3, 2012).]

#### **8.10 PRIOR PATENT – IDENIX PROPOSAL**

Gilead contends that the asserted claims of the ‘597 patent are anticipated by Merck’s ‘224 patent. In addition to the requirements on anticipation and priority that I have instructed you on, in order for a prior patent to anticipate a claimed invention, the prior patent must allow a person of ordinary skill in the art to practice the claimed invention without undue experimentation and sufficiently describe the claimed invention. Therefore, to find anticipation by the Merck patent, you must also find that Gilead has proven by clear and convincing evidence that the Merck patent enables a person of ordinary skill in the art to practice Dr. Sommadossi and Dr. La Colla’s invention without undue experimentation and sufficiently describes their invention. I have previously instructed you on the written description and enablement requirements.

[Source: 35 U.S.C. § 102(e); *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008); *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1036-37 (Fed. Cir. 2001).]

### **8.11 PRIORITY DATE – GILEAD PROPOSAL**

In this case you must also determine the “priority date” for the ’597 patent in suit. Idenix bears the burden of coming forward with evidence that the ’597 patent is entitled to a priority date that precedes its actual June 20, 2003 filing date.

Gilead alleges that Idenix’s claims at issue are invalid because of certain work by Merck. Separately, Gilead alleges that Idenix’ claims at issue are invalid based on a Merck patent that contains material disclosed in a Merck patent application filed on January 22, 2001. Idenix alleges that the claims at issue are not invalid, in part, because the claims are entitled to a priority date that precedes the Merck work and Merck patent application.

A patent or patent application may be entitled to a priority date that is earlier than the actual filing date only if the patent specifically references an earlier filed application and that earlier application contains the required written description and enablement support for the patent claims, which, as construed, cover methods of treatment of Hepatitis C that are actually effective, using compounds that include a 2’-methyl (up) but not hydrogen at 2’ down. Whether there is adequate enablement and written description support in the earlier application is evaluated as of the filing date of the earlier application, from the perspective of a person of ordinary skill in the art. I previously provided instructions to you on the written description and enablement requirements, which you should apply in making your determination of Idenix’s priority date.

Idenix’s ’597 patent has an actual filing date of June 20, 2003. In order to determine whether the Merck work and/or the Merck patent application is in fact prior art, you must consider whether Idenix’s ’597 patent is entitled to the benefit of the May 23, 2000 provisional application, or the benefit of its May 23, 2001 utility application, or neither. You may find that the ’597 patent in suit is entitled to either of these dates as its priority date, or you may find that

the patent in suit is not entitled to any earlier priority date, in which case, the priority date is the actual filing date of June 20, 2003. Your determination of the '597 patent's priority date may impact whether or not the Merck work and/or Merck patent is prior art to the '597 patent.

**Authority:** Federal Circuit Bar Association Model Patent Jury Instructions § 4.2a (2016); 35 U.S.C. §§ 112, 120; *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991); *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (“[T]he specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.”); *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1303-06 (Fed. Cir. 2008); *Technology Licensing Corp. v. Videotek, Inc.*, 545 F. 3d 1316, 1328-29 (Fed. Cir. 2008); *Research Corp. Techs. v. Microsoft Corp.*, 627 F. 3d 859, 870 (Fed. Cir. 2010); *In re Katz Interactive Call Processing Patent Litigation*, 639 F. 3d 1303, 1322 (Fed. Cir. 2011).



### **8.12 ANTICIPATION – PRIOR INVENTION – GILEAD PROPOSAL**

Gilead contends that certain claims of the '597 patent are invalid because Merck first made or invented the invention described in those claims. If Merck made or invented the subject matter covered by those claims of the '597 patent before Idenix, then these claims were “anticipated” by the other invention and are invalid. Gilead must prove anticipation by clear and convincing evidence.

Determining whether there was a prior invention requires consideration of conception and reduction to practice. The person who first conceived of the claimed invention and first reduced it to practice is the first inventor unless that person abandoned, suppressed, or concealed the invention. Conception is the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is to be applied in practice. Reduction to practice occurs either as of the filing of a patent application that provides an adequate written description for the claimed invention or when the invention was actually made and was shown to work for its intended purpose. In this case, Idenix’s earliest reduction to practice date is the same as whatever you determine the priority date to be for the '597 patent.

The invention was not abandoned, suppressed, or concealed unless the inventor unreasonably delayed in making the invention publicly known. Mere delay, without more, is not sufficient to establish abandonment, suppression or concealment. A reasonable pause in active work does not constitute abandonment, suppression, or concealment where the facts are consistent with a continuing commitment to pursuing the project to the full extent conditions allowed.

If one person conceived of the claimed invention first, but reduced it to practice second, that person is the first inventor only if that person (a) began to reduce the claimed invention to practice before the other party conceived of it and (b) continued to work with reasonable

diligence to reduce it to practice from a time just before the other party's conception.

Reasonable diligence means that the inventor worked continuously on reducing the invention to practice. Interruptions caused by the everyday problems and obligations of the inventor or others working with him or her do not prevent a finding of reasonable diligence.

**Authority:** *ICU Medical, Inc. v. Rymed Techs., Inc.*, Case No. 07-468-LPS, Doc. No. 492 at § 5.3; *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572 (Fed. Cir. 1996); *Fleming v. Escort, Inc.*, 774 F.3d 1371, 1378 (Fed. Cir. 2014); *Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1342 (Fed. Cir. 2001).

### **8.13 ANTICIPATION – PREVIOUSLY PUBLISHED – GILEAD PROPOSAL**

Gilead contends that certain claims of the '597 patent are invalid because they were not new and were “anticipated” by a Merck patent.

An invention is not new if the claimed invention was described in a patent granted on an application for patent by another, filed in the United States, and the application was filed before Idenix's date of invention. The date of invention is either when the invention was reduced to practice or when it was conceived, provided the inventor was diligent in reducing the invention to practice. In this case, Idenix's earliest reduction to practice date is the same as whatever you determine the priority date to be for the '597 patent. You should determine conception, diligence, and reduction to practice here based on the same standards that I gave you previously when discussing prior invention.

For the claim to be invalid because it is not new, Gilead must show by clear and convincing evidence that all of the requirements of that claim were present in a single previous printed publication or patent. We call these things “anticipating prior art.” To anticipate the invention, the prior art does not have to use the same words as the claim, but all of the requirements of the claim must have been disclosed, either stated expressly or implied to a person having ordinary skill in the art in the technology of the invention, so that looking at that one reference, that person could make and use the claimed invention.

**Authority:** Federal Circuit Bar Association Model Patent Jury Instruction 4.3(a-1), 4.3(b-1); 35 U.S.C. § 102.

## **8.14 OBVIOUSNESS**

### **GILEAD PROPOSAL**

Gilead contends that all of the asserted claims of the '597 patent are invalid as obvious. In order to be patentable, an invention must not have been obvious to a person of ordinary skill in the art at the time the invention was made. The issue is not whether the claimed invention would be obvious today to you, as a layperson, to me as a judge, or to a genius in the art, but whether it would have been obvious to one of ordinary skill in the art at the time it was made.

In determining obviousness or non-obviousness of the subject matter of each of the asserted claims, you should take the following steps:

1. Determine the scope and content of the prior art;
2. Identify the differences, if any, between each asserted claim and the prior art;
3. Determine the level of ordinary skill in the pertinent art at the time the invention of the patent was made;
4. Consider objective factors of non-obviousness.

In addition, you may consider whether there was an apparent reason to combine or modify the prior art references in the fashion claimed by the patent at issue, but in doing so, you must guard against slipping into the use of hindsight.

I will explain each of these factors in more detail in a moment. Against this background, you will then decide whether the subject matter of each asserted claim would have been obvious or unobvious to a person of ordinary skill in the pertinent art.

**Authority:** *Fairchild Semiconductor Corp. v. Power Integrations, Inc.*, Case No. 12-540-LPS (D. Del.), D.I. 400 (Final Jury Instruction 6.3).

### **IDENIX PROPOSAL<sup>6</sup>**

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<sup>6</sup> Idenix objects to Gilead's § 103 instructions in total despite providing this counter-proposal.

Gilead contends that if all of the elements of the asserted claims of the '597 patent are not found in Dr. Wolanski's or Dr. Olsen's alleged inventions, then you should consider whether their work renders the claims obvious. Gilead bears the burden of proving obviousness by clear and convincing evidence, and Gilead's proof is limited to these specific alleged prior inventions. If you reach the question of obviousness over these specific alleged prior inventions, you must consider the following objective evidence which may tend to show non-obviousness of the asserted claims of the '597 patent, including:

1. Commercial success of products covered by the '597 patent;
2. A long felt need in the art which was satisfied by the invention of the '597 patent;
3. The failure of others to make the invention;
4. Copying of the invention by others in the field;
5. Unexpected results achieved by the invention;
6. Praise of the invention by the infringer or others in the field;
7. Expressions of disbelief or skepticism by those skilled in the art upon learning of the invention; and
8. Whether the inventor proceeded in a direction contrary to the accepted wisdom of those skilled in the art.

**8.14.1. SCOPE AND CONTENT OF THE PRIOR ART – GILEAD PROPOSAL**

As I just instructed you, in deciding whether or not the claimed invention is obvious to one of ordinary skill in the art, you must first determine the scope and content of the prior art.

This means that you must determine what prior art is reasonably pertinent to the particular problem with which the inventor was faced. Prior art is reasonably pertinent if it is in the same field as the claimed invention or is from another field that a person of ordinary skill

would look to in trying to solve the problem the named inventor was trying to solve. Prior art can include the following:

1. Prior patents that issued before the critical date for a particular patent;
2. Prior publications having a publication date before the critical date for a particular patent;
3. U.S. Patents that have a filing date prior to the critical date for a particular patent;
4. Anything in public use or on sale in the United States before the critical date for a particular patent;
5. Anything that was publicly known or used by others in this country before the date of the invention of a particular patent.
6. Any of Merck's work (as evidenced by testimony, documents, publications, or patents) that you have found was a prior invention or that you find to be indicative the level of ordinary skill in the art.

**Authority:** *Fairchild Semiconductor Corp. v. Power Integrations, Inc.*, Case No. 12-540-LPS (D. Del.), D.I. 400 (Final Jury Instruction 6.3.1); *Newell Companies, Inc., v. Kenney Mfg. Co.*, 864 F.2d 757, 766 & n.12 (Fed. Cir. 1988); *Thomas & Betts Corp. v. Litton Sys., Inc.*, 720 F.2d 1572, 1580-81 (Fed. Cir. 1983).

#### 8.14.2. LEVEL OF ORDINARY SKILL – GILEAD PROPOSAL

Next, you are to determine the level of ordinary skill in the art to which the claimed inventions pertain at the time the claimed inventions were made. A person of ordinary skill is not the inventor, but rather a hypothetical person who is presumed to be aware of all the prior art at the time of the invention. Factors to be considered in determining the level of ordinary skill in the pertinent art include the educational level of the inventors, the types of problems encountered in the art, the prior art patents and publications, the activities of others and prior art solutions to the problems encountered by the inventors, the sophistication of the technology, and the education of others working in the field.

**Authority:** *Fairchild Semiconductor Corp. v. Power Integrations, Inc.*, Case No. 12-540-LPS (D. Del.), D.I. 400 (Final Jury Instruction 6.3.2).

**8.14.3. INDEPENDENT INVENTION BY OTHERS – GILEAD  
PROPOSAL**

The simultaneous or near simultaneous invention by two or more persons working independently may or may not be an indication of obviousness when considered in light of all the circumstances.

**Authority:** *Fairchild Semiconductor Corp. v. Power Integrations, Inc.*, Case No. 12-540-LPS (D. Del.), D.I. 400 (Final Jury Instruction 6.3.3).



**8.14.4. OBJECTIVE CRITERIA CONCERNING OBVIOUSNESS –  
GILEAD PROPOSAL**

Lastly, in making your decision as to the obviousness or non-obviousness of the claimed inventions, you must consider the following objective evidence which may tend to show nonobviousness of the patent claims at issue (sometimes called “secondary considerations”):

1. Commercial success of products covered by the patents-in-suit;
2. A long felt need in the art which was satisfied by the invention of the patent-in-suit;

However, there must be a connection (i.e., a nexus) between the evidence showing any of these factors and the claimed invention if this evidence is to be given weight by you in arriving at your conclusion on the obviousness issue. For example, if the asserted claims of the ’597 patent cover both a commercially successful treatment for HCV and other treatments for HCV treatments that were not commercially successful, then commercial success would have no relation to the issue of obviousness.

**Authority:** *Fairchild Semiconductor Corp. v. Power Integrations, Inc.*, Case No. 12-540-LPS (D. Del.), D.I. 400 (Final Jury Instruction 6.3.5).

## **9. PATENT DAMAGES**

### **9.1 PATENT DAMAGES GENERALLY – AGREED IN PART**

If you find that one or more of the asserted claims are not invalid, you must determine the amount of money damages to be awarded to Idenix for the infringement. I will now instruct you about the measure of damages. **[Idenix proposal: Patent law provides that in the case of infringement of a valid patent claim, the owner of the patent shall be awarded damages adequate to compensate for the infringement. Damages are compensation for all losses suffered as a result of the infringement. There are different types of damages that the patent owner may be entitled to recover. In this case, Idenix seeks a reasonable royalty based upon Gilead's sales of SOVALDI® and HARVONI®.]**

**Idenix must prove each element of its damages, including the amount of the damages, by a preponderance of the evidence, which means it is more likely than not that Idenix has proven its damages.**

**If proven by Idenix, the amount of those damages must compensate Idenix for the infringement. The damage award cannot be less than a reasonable royalty. The reasonable royalty rate may not be purely speculative. You may not add anything to the amount of damages to punish an accused infringer or to set an example. You also may not add anything to the amount of damages for interest. Damages need not be proven with mathematical precision. [Idenix Source: *Helios Software, LLC et al. v. Spectorsoft Corp.*, 12-081-LPS (June 19, 2015).]**

**[Gilead proposal: By instructing you on damages, I am not suggesting which party should win this case, on any issue. If you find that the asserted claims are all invalid, then Idenix is not entitled to any damages.]**

**The fact that I am instructing you on damages does not mean that the Court believes that one party or the other should win this case. My instructions about damages are for your guidance in the event you find in favor of Idenix.]**

**Idenix has the burden to establish the amount of its damages by a preponderance of the evidence. In other words, you should award only those damages that Idenix establishes that it more likely than not suffered. While Idenix is not required to prove its damages with mathematical precision, it must prove them with reasonable certainty. You may not award damages that are speculative, damages that are only possible, or damages that are based on guesswork. In this case, Idenix seeks a reasonable royalty based upon Gilead's past sales of SOVALDI® and HARVONI® and reserves the right to seek additional damages for future sales from the Court. Gilead contends that, if the patent is valid, then the reasonable royalty should take the form of a one-time, lump sum payment for the right to practice the '597 patent throughout its entire term. If you award damages, you will need to decide between these two alternatives. But, regardless of the type of damages you may choose to award, you must be careful to ensure that award is no more or no less than the value of the patented invention.**

**Gilead Authority: Federal Circuit Bar Association, Model Patent Jury Instructions 6.1.]**

## **9.2 PATENT DAMAGES – REASONABLE ROYALTY – AGREED IN PART**

A royalty is a payment made to a patent holder in exchange for the right to make, use, or sell the claimed invention. A reasonable royalty is the amount of royalty payment that a patent holder and the infringer would have agreed to in a hypothetical negotiation taking place at a time prior to when the **[Gilead: assumed]** infringement first began. In considering this hypothetical negotiation, you should focus on what the expectations of Idenix and Gilead would have been had they entered into an agreement at that time, and had they acted reasonably in their negotiations.

In determining this, you must assume that the parties believed the patent was valid and infringed and that the parties were willing to enter into an agreement. The reasonable royalty you determine must be a royalty that would have resulted from the hypothetical negotiation, and not simply a royalty either party would have preferred.

**[Gilead proposal: Evidence of things that happened after the infringement first began can be considered in evaluating the reasonable royalty only to the extent that the evidence aids in assessing what royalty would have resulted from a hypothetical negotiation. Although evidence of the actual profits an alleged infringer made may be used to determine the anticipated profits at the time of the hypothetical negotiation, the royalty may not be limited or increased based on the actual profits the alleged infringer made.]**

**Gilead Authority:** Helios Software, LLC et al. v. Spectorsoft Corp., 12-081-LPS (June 19, 2015), D.I. 621 at 67; Federal Circuit Bar Association, Model Patent Jury Instructions 6.6.]

### **9.3 PATENT DAMAGES: LUMP SUM OR RUNNING ROYALTY – GILEAD PROPOSAL<sup>7</sup>**

A reasonable royalty can be calculated in several different ways and it is for you to determine which way is the most appropriate based on the evidence you have heard. Idenix contends that you should calculate the reasonable royalty based on what is called an “ongoing royalty.” To calculate an ongoing royalty, you must first determine the “base,” that is, the product on which the infringer is to pay. You then need to multiply the revenue that Gilead obtained from that base by the “rate” or percentage that you find would have resulted from the hypothetical negotiation.

Gilead contends that, if you find the patent valid, you should calculate the reasonable royalty by determining a one-time lump sum payment that Gilead would have paid at the time of the hypothetical negotiation for a license covering all sales of any product covered by the ’597 patent, both past and future. This differs from payment of an ongoing royalty because, with an ongoing royalty, the licensee pays based on the revenue of actual licensed products it sells. When a one-time lump sum is paid, the infringer pays a single price for a license covering both past and future infringing sales.

It is up to you, based on the evidence, to decide what type of royalty is appropriate in this case for the life of the patent.

Authority: Model Patent Jury Instructions for the Northern District of California, Instruction 5.7.

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<sup>7</sup> Idenix objects to this instruction being given.

#### **9.4 FACTORS FOR DETERMINING REASONABLE ROYALTY – AGREED**

In determining the reasonable royalty, you should consider all the facts known or available to the parties at the time the infringement began. Some of the kinds of factors that you may consider in making your determination are:

- 1) The royalties received by Idenix for the licensing of the '597 patent, proving or tending to prove an established royalty.
- 2) The rates paid by Gilead for the use of other patents comparable to the '597 patent.
- 3) The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.
- 4) Idenix's established policy and marketing program to maintain its right to exclude others from using the patented invention by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that exclusivity.
- 5) The commercial relationship between Idenix and Gilead at the time of the hypothetical negotiation, such as whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter.
- 6) The effect of selling the patented product in promoting sales of other products of Gilead; the existing value of the invention to Idenix as a generator of sales of its non-patented items; and the extent of such derivative or convoyed sales.
- 7) The remaining life of the '597 patent and the term of the license.
- 8) The established profitability of the product made under the infringed '597 patent, its commercial success, and its current popularity.

- 9) The utility and advantages of the patented property over the old modes or devices, if any, that had been used for working out similar results.
- 10) The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by Idenix at the time of the hypothetical negotiation; and the benefits to those who have used the invention.
- 11) The extent to which Gilead has made use of the invention; and any evidence probative of the value of that use.
- 12) The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.
- 13) The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks or significant features or improvements added by Gilead.
- 14) The opinion testimony of qualified experts.
- 15) The amount that a licensor (such as Idenix) and a licensee (such as Gilead) would have agreed upon at the time the infringement began if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee who desired as a business proposition to obtain a license to manufacture and sell a particular product embodying the patented invention would have been willing pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.

No one factor is dispositive and you can and should consider the evidence that has been presented to you in this case on each of these factors. You may also consider any other factors which in your mind would have increased or decreased the royalty Gilead would have been willing to pay and Idenix would have been willing to accept, acting as normally prudent business people.



#### **9.5 REASONABLE ROYALTY – TIMING – IDENIX PROPOSAL**

The relevant date for the hypothetical reasonable royalty negotiation is at the time infringement began. In this case, that date would be December 6, 2013, when Gilead received approval to begin selling SOVALDI®.

## **9.6 DAMAGES – APPORTIONMENT**

### **IDENIX PROPOSAL**

Traditional principles of apportionment do not apply under what is sometimes called the “Entire Market Value Rule” in cases involving a pharmaceutical product or its use. The drug as a whole is the smallest salable patent-practicing unit. In this case, where infringement is assumed and the asserted claims cover the use of the accused drug as a whole, there is no non-infringing feature in the drug and traditional principles of apportionment do not apply.

[Source: *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1338 (Fed. Cir. 2015).]

### **GILEAD PROPOSAL**

A damages award must reflect the value you find attributable to the patented inventions. The evidence tending to separate or apportion damages between the patented features and unpatented features must be reliable and tangible, and not conjectural or speculative. You may award damages based only on what is directly attributable to the value of the ’597 patent. You may not award damages that are attributable to unpatented features of the Accused Products. Idenix bears the burden of establishing amounts directly attributable to the patented features.

Authority: Final Jury Instructions, *Greatbatch Ltd. v. AVX Corporation*, 13-723-LPS (January 25, 2016), D.I. 621 at 59.

**9.7 DAMAGES – COMPARABLE LICENSES – GILEAD PROPOSAL<sup>8</sup>**

When determining a reasonable royalty, you may consider evidence concerning the amounts that other parties have paid for rights to the patent in question, or for rights to similar technologies. A license agreement must not be perfectly comparable to a hypothetical license that would be negotiated between Idenix and Gilead in order for you to consider it. However, if you choose to rely upon evidence from any other license agreements, you must account for any differences between those licenses and the hypothetically negotiated license between Idenix and Gilead, in terms of the technologies and economic circumstances of the contracting parties, when you make your reasonable royalty determination. Settlement agreements can be pertinent to the issue of reasonable royalties, and the most reliable license may arise out of litigation.

Authority: AIPLA Model Patent Jury Instruction 11.21 (2015); *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1225-29 (Fed. Cir. 2014); *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1330-31 (Fed. Cir. 2014); *Apple Inc. et al v. Motorola Inc.*, 757 F.3d 1286, 1325-26 (Fed. Cir. Apr. 25, 2014); *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 77-81 (Fed. Cir. 2012); *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869-70 (Fed. Cir. 2010); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 129, 1336 (Fed. Cir. 2009).

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<sup>8</sup> Idenix objects to this instruction being given.

**10. DELIBERATION AND VERDICT**

**10.1 INTRODUCTION – AGREED**

That concludes the part of my instructions explaining the rules for considering some of the testimony and evidence. Now let me finish up by explaining some things about your deliberations in the jury room, and your possible verdicts.

Once you start deliberating, do not talk to the jury officer, or to me, or to anyone else except each other about the case. If you have any questions or messages, you must write them down on a piece of paper, sign them, and then give them to the jury officer. The officer will give them to me, and I will respond as soon as I can. I may have to talk to the lawyers about what you have asked, so it may take some time to get back to you. Any questions or messages normally should be sent through your foreperson, who by custom of this Court is Juror No. 1.

One more thing about messages. Do not ever write down or tell anyone how you stand on your votes. For example, do not write down or tell anyone that you are split 4-4, or 6-2, or whatever your vote happens to be. That should stay secret until you are finished.

## **10.2 UNANIMOUS VERDICT – AGREED**

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, it is necessary that each juror agree to the verdict. Your verdict must be unanimous.

It is your duty, as jurors, to consult with one another and to deliberate with a view towards reaching an agreement, if you can do so without violence to your individual judgment. Each of you must decide the case for yourself, but do so only after an impartial consideration of the evidence with your fellow jurors. In the course of your deliberations, do not hesitate to reexamine your own views and change your opinion, if you become convinced it is erroneous. But do not surrender your honest conviction as to the weight or effect of evidence solely because of the opinion of your fellow jurors, or for the purpose of returning a verdict. Remember at all times that you are not partisans. You are judges – judges of the facts. Your sole interest is to seek the truth from the evidence in the case.

A form of verdict has been prepared for you, and you have been provided a copy. I will review it with you in a moment. You will take this form to the jury room and when you have reached unanimous agreement as to your verdict, you will have your foreperson fill in, date and sign the form. You will then return to the courtroom and your foreperson will give your verdict to my deputy who will read aloud your verdict.

It is proper to add the caution that nothing said in these instructions and nothing in the form of the verdict is meant to suggest or convey in any way or manner any intimation as to what verdict I think you should find. What the verdict shall be is the sole and exclusive duty and responsibility of the jury.

[Source: Final Jury Instructions, *Greatbatch Ltd. v. AVX Corporation, et al.*, 13-723-LPS (January 25, 2016).]

### **10.3 DUTY TO DELIBERATE – AGREED**

Now that all the evidence is in and the arguments are completed, you are free to talk about the case in the jury room. In fact, it is your duty to talk with each other about the evidence, and to make every reasonable effort you can to reach unanimous agreement. Talk with each other, listen carefully and respectfully to each other's views and keep an open mind as you listen to what your fellow jurors have to say. Try your best to work out your differences. Do not hesitate to change your mind if you are convinced that other jurors are right and that your original position was wrong. But do not ever change your mind just because other jurors see things differently, or just to get the case over with. In the end, your vote must be exactly that – your own vote. It is important for you to reach unanimous agreement, but only if you can do so honestly and in good conscience.

No one will be allowed to hear your discussions in the jury room, and no record will be made of what you say. So you should all feel free to speak your minds.

Listen carefully to what the other jurors have to say, and then decide for yourself.

#### **10.4 SOCIAL MEDIA – AGREED**

During your deliberations, you must not communicate with or provide any information to anyone by any means about this case. You may not use any electronic device or media, such as the telephone, cell phone, smartphone, tablet, or computer, the Internet, any Internet service, any text or instant messaging service, any Internet chat room, blog, or website such as Facebook, MySpace, LinkedIn, YouTube, or Twitter, to communicate to anyone any information about this case or to conduct any research about this case until I accept your verdict.

In other words, you cannot talk to anyone on the phone, correspond with anyone, or electronically communicate with anyone about this case. You can only discuss the case in the jury room with your fellow jurors during deliberations.

**10.5 COURT HAS NO OPINION - AGREED**

Let me finish by repeating something I said to you earlier. Nothing that I have said or done during this trial was meant to influence your decision in any way. You must decide the case yourselves based on the evidence presented.